III. REJECTION OF CLAIMS 1-9 UNDER THE JUDICIALLY CREATED DOCTRINE OF DOUBLE PATENTING OVER CLAIMS 1-22 OF US PATENT 6,027,779, CLAIMS 1-40 OF US PATENT 6,025,044 AND CLAIMS 1-2 OF US PATENT 6,027,811

A new terminal disclaimer is submitted herewith, disclaiming "all parent patents" as request d by the Examiner. If this disclaimer is unsatisfactory, the Examiner is respectfully requested to telephone the undersigned representative in order that any remaining differences may be resolved.

IV. REJECTION OF CLAIMS 1-9 UNDER USC 103(a) AS UNPATENTABLE OVER BUCK et al., US 4,925,710 IN VIEW OF GORE, US 3,593,566 AND SOLTESZ, US 5,254,107.

Buck et al. teach the manufacture of wire insulation and tubes which might be used for automotive cables or medical catheters. Gore teaches the manufacture of ePTFE while Soltesz teaches the construction of a catheter tube having a middle layer of wire reinforcement which is enclosed by inner and outer thermoplastic sections wherein the inner section may be PTFE or the like. The claims are rejected as obvious over the combination of the three cited references. The Examiner has concluded that one of ordinary skill would have been motivated to use or easily adapt the teachings of Gore for the purpose of obtaining a non-porous catheter balloon comprising permeable and porous ePTFE (having a micorstructure of nodes and fibrils) provided with a non-porous coating, and that the present invention is an obvious modification of the cited art.

Applicants respectfully disagree with the Examiner's conclusion as follows.

First, none of the three cited references teach the construction of a thin and very flexible catheter balloon having the claimed construction. Indeed, not one of the cited references makes any suggestion whatsoever of making a catheter balloon of any type.

Further, there is no reason to combine any of the references. Buck et al. teach an *impermeable* tube construction. They teach that the fundamental material for their tube is a fluoropolymer such as TFE that may optionally be provided with fillers. The fillers are stated to be of any shape (col. 4, lines 30-34) including "spheres, rods, fibers, random angular shapes, etc...."
They subsequently state (col. 4, lines 48-50) that spherical fillers may be either solid or hollow. It is only the hollow spheres out of all of the recited filler shapes that would provide any porous character to their tube material, and clearly these are closed-cells that are not interconnected in any way with the clear result that the tube material of Buck et al. has to be impermeable. As such, Buck et al. unquestionably teach away from the use of permeable materials and there cannot be any suggestion to combine with a ref rence that teaches permeable materials.

Likewise, Gore only t aches permeable materials. There is no suggestion in Gore to take the permeable ePTFE and render it impermeable with a coating in order to take advantage of its great flexibility and very good strength in an impermeable form as with the present invention. The *only*

teaching of the construction of an ePTFE tube in Gore (Example 8 at col. 14) includes a data table (Table 8) summarizing the attributes of the tube made according to this example. One of these attributes is specifically a description of the air permeability of the tube. There is simply no suggestion to render the permeable ePTFE tube of Gore impermeable. Indeed, there is no reason to combine the permeable material of Gore with the impermeable material of Buck et al.

Soltesz teaches a medical catheter tube made from various polymers (which may be PTFE) wherein the catheter tube is made up of two sections having different properties and made from different polymers, with the two sections abutted end-wise so that the resulting tube has different characteristics in the two sections. The wall of the tube is provided with a reinforcing material such as braided wire or braided fibers. Inner and outer layers of polymeric tubing sandwich the reinforcing material, neither of which polymer layers are suggested in any way to be porous. Soltesz makes absolutely no suggestion to incorporate a permeable, microporous material. While the Soltesz tube is stated to be flexible with regard to bending, there is no suggestion that the tube should be flexible to the extent that it is readily collapsible as is the tube of the present invention. Indeed, catheter tubes are well known to those of skill in the art of medical tubings to be typically rigid enough to offer good crush resistance in order to resist any loss of cross section that would impair the transfer of a fluid to a living body. All of the teachings of both Soltesz and Buck et al. are consistent with this common character of catheter tubes. There is simply nothing in either of these catheter teachings to suggest a tube that is adequately thin and highly flexible to the extent shown in Figures 14A, 16A and 16B of the present application (please note the specification of an earlier issued parent of the present application, US 6,027,779, at col. 9, lines 57-66).

The Examiner cited *In re Betz*, "the test of obviousness is not express suggestion of the claimed invention in any and all of the references but rather what the references taken collectively would suggest to those of ordinary skill in the art presumed familiar with them." The Applicants do not disagree with this in any way. However, without the benefit of hindsight, the man of ordinary skill would not derive the present invention from the collective cited references. None of them teach or suggest making a catheter balloon in any form, and certainly not from a permeable material rendered impermeable with a coating. The two catheter references do not suggest the use of permeable, microporous materials in any way, and certainly do not suggest the highly flexible and readily collapsible character of the present tube in any way. Indeed, the man of skill would find no reason or suggestion to combine Gore with either of the other two references. Likewise, he would find no suggestion in Gore to make an impermeable balloon material by coating the permeable Gore material and thus completely alter the fundamental permeable character taught by Gore to be desirable. Soltesz and Buck et al. teach away from the use of materials such as those of Gore, and vice versa. The claims in their present form are not obvious over the cited references to the man of ordinary skill.

CONCLUSION

The applicants believe that their claims are in good and proper form and are patentabl over the cited art. As such, the applicants respectfully request reconsideration, allowance of the claims and passage of the case to issuance.

Respectfully Submitted,

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